

March 26, 2002

The Honorable Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration
Room 14-71
5600 Fishers Lane
Rockville, Maryland 20782

Lester
Dear Dr. Crawford:

I appreciate your responding to Representative Farr's question (at the March 21 hearing) about the status of our 1997 petition on caffeine labeling by saying that the petition is now on your "radar screen" and that you would give him a timetable of FDA's action on it.

Indeed, over the past 20 years, the FDA itself has been advising pregnant women to "avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly."¹ More recently, physicians have routinely advised pregnant women "to avoid caffeine-containing foods and drugs whenever possible. If you can't give up caffeine during pregnancy, keep your intake below 200 milligrams."² That is because studies have correlated the consumption of the amount of caffeine in several cups of coffee with low birth weight, miscarriages, and other adverse effects on pregnancy. One pregnancy book, for example, tells women that "Consumed in high amounts (500 milligrams or more daily), caffeine increases the amount of time a fetus spends in an active, awake state and may cause a decrease in your baby's weight and head circumference."³

Last fall the British government issued similar advice after a review by independent experts, who concluded that "caffeine intakes above 300 mg/day may be associated with low

¹ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Caffeine and Pregnancy* (FDA) 81-1081. See also Rebecca D. Williams, "Healthy Pregnancy, Healthy Baby," *FDA Consumer Magazine* (March-April 1999).

² Robert V. Johnson, M.D., ed. *Mayo Clinic Complete Book of Pregnancy & Baby's First Year* (1994) at 101 (enclosed). See also Tracie Hotchner, *Pregnancy & Childbirth* (1997) at 76; Arlene Eisenberg, Heidi E. Murkoff, and Sandee E. Hathaway, *What to Expect When You're Expecting* (1996) at 60 (enclosed).

³ Johnson at 101.


birth weight and, in some cases, miscarriage.”⁴ The US Pharmacopeia, a private group that sets standards for drug manufacturing and dosage, says that pregnant women should consume no more than 300 milligrams of caffeine daily.

Almost five years ago the American Medical Association called on the FDA to require that the amount of caffeine in the product be declared on the label (see enclosed resolution). Yet the FDA has taken no action on a petition that we filed in July 1997 asking that the FDA require disclosure of the caffeine content of food and beverages.⁵

Thus, pregnant women (and others⁶) still cannot know how much caffeine is in a serving of a particular food or beverage, such as coffee, tea, colas and other soft drinks, caffeinated water, ice cream, frozen yogurt, yogurt, chocolate milk, and chocolate candies.

In conclusion, on behalf of our 800,000 members I urge you to immediately initiate a rulemaking to require the disclosure of the amount of caffeine in a food or beverage.

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director

enclosures

⁴ Food Standards Agency of United Kingdom October 10, 2001 press release (enclosed).

⁵ CSPI filed this 1997 petition after the FDA officially denied in October 1996 the petition CSPI had filed in 1979.

⁶ Caffeine can also adversely affect both non-pregnant women because of its effect on bone-mineral metabolism and children because of its possible impact on anxiety and restlessness. See enclosed letter of February 13, 2001 from the American Psychological Association to the FDA supporting CSPI's petition.